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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,630	EINAT ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/9/2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,14-20,28-30 and 32* is/are pending in the application.

4a) Of the above claim(s) *17,19,20 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,14-16,18 and 32* is/are rejected.

7)☒ Claim(s) *28 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group IV, claims 13-18 and 28-30, polypeptide sequence of SEQ ID NO: 24, species of a polypeptide having a molecule weight of 10 kD to 100 kD (claim 16) and species of the first 663 amino acids (claim 29) in Paper No. 11 is acknowledged. The traversal is on the ground(s) that: (1) Groups IV and V "are drawn to the same patentable invention." since "[T]echniques of raising antibodies, including monoclonal antibodies, are well known and the Patent and Trademark Office routinely rejects claims to monoclonal antibodies as being obvious if the protein against which it is specific is known to the prior art." ; (2) "[I]f the elected protein claims proceed to issue, any patent issuing on the antibody would have to be subject to an obviousness-type double patenting rejection"; (3) " this identical issue has already been made the subject of a petition to the Commissioner by the undersigned with respect to another case and Deputy Director Mary C. Lee, in a decision published as *In re Gold*, 42 US PQ 2d 1095 (comm'r Pats 1996) confirmed that, in such a circumstance, restriction requirement is not applicable."; (4) " at least SEQ ID Nos: 11, 14, 16, and 24 and the product of claim 32, should be considered to be directed to the same invention (i.e., human OCP)" since "SEQ ID Nos: 11, 14, 16, and 24, as well as the polypeptide expressed by the expression plasmid of claim 31, are all minor variants of the same human OCP protein" which "have the same function and are substantially the same sequence.".

The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same

such that Groups IV and V will be examined together. First, the examiner agrees with applicant "[T]echniques of raising antibodies, including monoclonal antibodies, are well known". However, the examiner does not agree with applicant that making monoclonal antibodies is obvious to one having ordinary skill in the art at the time the invention was made if the protein is known and "[I]f the elected protein claims proceed to issue, any patent issuing on the antibody would have to be subject to an obviousness-type double patenting rejection.". According to MPEP 808.02, "the related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c) - § 806.05(I), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following": (1) separate classification thereof; (2) A separate status in the art when they are classifiable together; and (3) a different field of search. Since a polypeptide and an antibody elicited by the polypeptide have different classification and have different amino acid sequences, and require different field of searches, restriction requirement is proper. Second, although, in *In re Gold*, 42 US PQ 2d 1095, applicant's petition was granted, editor's note in page 1095 clearly states " [T]he U.S Patent and Trademark Office has not designated this decision as prepared for Publication. It is not binding precedent of the Commissioner of Patents and Trademarks.". This statement indicates that decision made in *In re Gold*, 42 US PQ 2d 1095 is not published and is not an universal policy of the Patent office. Therefore, the examiner is not forced to follow this decision (see attached *In re Gold*, 42 US PQ 2d 1095). Third, the examiner agrees to examine SEQ ID Nos: 23 and 24 together since SEQ ID NO: 23 is a nucleotide sequence which encodes a polypeptide consisting of SEQ ID NO: 24. Fourth, the examiner agrees with applicant that SEQ ID Nos: 11, 14, 16, and 24 are minor

variants of the same human OCP protein. However, applicant does not provide evidence to show that all variants have the same function since it is known that substitution or insertion or deletion of one or more amino acids on a protein can alter functions of a protein. Since these SEQ ID Nos. have different nucleotide sequences, they are considered to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. An expressed plasmid designated pCm-H-608-663-N-term can not be considered as a variant of the same human OCP protein since this plasmid does not appear to have an insert (see page 34). However, the examiner will agree to examine SEQ ID Nos: 11, 14, 16, and 24 together if applicant should submit evidence or identify such evidence now of record showing SEQ ID Nos: 11, 14, and 16 to be obvious variants of SEQ ID NO: 24 or clearly admit on the record that this is the case.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The examiner notes that applicant filed IDS on June 26, 2002. However, the examiner can not locate IDS and form 1449.

Deposit Requirement

3. Applicant's referral to the deposit of ATCC with Accession NO. PTA-3638 on page 34 of the specification is insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. Furthermore, the specification should be amended to reflect the change in the address

of the ATCC, whose new address is 10801 University Boulevard Manassas, VA 20110-2209, USA.

If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by Applicant, Assignee, or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository, is required. This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty, as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.

Furthermore, unless deposit was made at or before the time of filing, a declaration filed under 37 CFR 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited material by its depository accession number, establish that the deposited material is the same as that described in the specification, and establish that the deposited material was in Applicant's possession at the time of filing. See In re Lundak, 27 USPQ 90.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance

of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request, or for the enforceable life of the patent, whichever is longer;

d) a test of the viability of the biological material at the time of the deposit was made, and that the test results indicated that said biological material was viable (see 37 CFR 1.807); and,

e) the deposit will be replaced it should ever become inviable.

Claim Objections

4. Claim 1 is objected to because of the following informality: SEQ ID NOs: 1, 3, 6, 20, and 22 should be deleted since applicant has elected SEQ ID NO: 24 for the examination as the result of the restriction requirement. As shown above, the examiner agrees to examine SEQ ID NO: 23 which is a nucleotide sequence which encodes a polypeptide consisting of SEQ ID NO: 24.

5. Claims 14 and 15 are objected to because of the following informality: "Adlican" should be deleted since applicant has elected SEQ ID NO: 24 (human OCP protein or human 608) for the

examination as the result of the restriction requirement and has not elected SEQ ID NO: 21 (sequence for Adlican protein) for the examination.

6. Claim 14 is objected to because of the following informality: "protein 608" should be replaced with "human protein 608" since applicant has elected SEQ ID NO: 24 (human OCP protein or human 608) for the examination as the result of the restriction requirement and has not elected protein 608 from any kind of species for the examination.

7. Claims 28 and 29 are objected to because of the following informality: applicant requires to delete other SEQ ID Nos. since applicant only elected SEQ ID NO: 24 for the examination as the result of the restriction requirement

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was made based on the best understanding of claims 1 and 32 although claims 1 and 32 are vague and indefinite (see the rejections under 35 USC 112, second paragraph).

Applicant is referred to the interim guidelines on written description published on December 21, 1999 in the Federal Register at Volume 64, Number 244, pp.71427-71440.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The specification (pages 1-78) provides adequate written descriptions for an isolated polypeptide encoded by a nucleic acid molecule consisting of SEQ ID NO: 23 (cDNA of human OCP protein or human protein 608 with 7770 nucleotides) and an isolated polypeptide consisting of SEQ NO: 24 (protein sequence of human OCP protein or human protein 608 with 2589 amino acids) (see SEQ ID NOs: 23 and 24) and SEQ ID NO: 23 incorporated in a plasmid designated pCm-H608-N-term (see page 34) wherein human OCP protein or human protein 608 is correlated with bone fraction healing (see pages 49-53). From Figure 13C, it appears that whole length whole length of cDNA and protein sequences of human OCP protein are 7833 nucleotides and 2611 ((7833/3) amino acids respectively although the specification does not specify whole length of cDNA and protein sequences of human OCP protein. Therefore, based on the lengths of

SEQ ID NOs: 23 and 24, these sequences are considered as a partial cDNA and a partial protein of human OCP protein respectively. However, the specification fails to adequately describe: (1) a isolated polypeptide encoded by a nucleic acid molecule comprising nucleotides having a sequence set forth in SEQ ID NO: 23 or its functional portion or its at least substantially homologous or identical sequences as recited in claim 1; (2) an polypeptide encoded by a nucleic acid molecule comprising nucleotides having any kind of sequence incorporated in a plasmid designated pCm-H-608-663-N-term or its complements or its functional portion or its at least substantially homologous or identical sequences as recited in claim 1; and (3) any kind of isolated polypeptide expressed by an expressed plasmid designated pCm-H-608-663-N-term as recited in claim 32. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998).

In this instant case, as described above, since SEQ ID NOs: 23 is a partial cDNA of human OCP protein, claimed partial cDNA do not include a disclosure of any open reading frame of which it would be a part of cDNA and would not be representative of the genus of cDNA because no information regarding the coding capacity of the cDNA molecule is disclosed, a

nucleic acid molecule in claim 1 was read as: (1) any kind nucleic acid that has SEQ ID NO: 23 and is larger than a nucleic acid consisting of SEQ ID NO: 23 (ie., a chromosome having SEQ ID NO: 23) or its functional portion; or (2) any kind of nucleic acid that has a polynucleotide which is at least substantially homologous or identical to SEQ ID NO: 23 (ie, a chromosome having a polynucleotide which is at least substantially homologous or identical to SEQ ID NO: 23); or (3) a nucleic acid molecule comprising nucleotides having any kind of sequence or its partial or full complements or its functional portion or its at least substantially homologous or identical sequences incorporated in a plasmid designated pCm-H-608-663-N-term. Since it has been known that a chromosome is consisted of a lot of different genes, an isolated polypeptide in claim 1 was read as: (1) a polypeptide encoded by any kind of gene located in the chromosome having SEQ ID NO: 23; or (2) a polypeptide encoded by any kind of genes located in the chromosome having polynucleotide which is at least substantially homologous or identical to SEQ ID NO: 23; or (3) any kind of polypeptide expressed by an expressed plasmid designated pCm-H-608-663-N-term. An isolated polypeptide in claim 32 was read as any kind polypeptide expressed by an expressed plasmid designated pCm-H-608-663-N-term since the claim does not specify which nucleic acid is inserted in the plasmid.

Although the specification adequately describes an isolated polypeptide encoded by a nucleic acid molecule consisting of SEQ ID NO: 23 (cDNA of human OCP protein or human 608 protein with 7770 nucleotides) and an isolated polypeptide consisting of SEQ NO: 24 (protein sequence of human OCP protein or human 608 protein with 2589 amino acids) and SEQ ID NO: 23 incorporated in a plasmid designated pCm-H608-N-term (see above), claims 1 and 32

encompass numerous unknown and unidentified polypeptides that miss from the disclosure. It is unclear what kind of functions of these polypeptides have and whether these polypeptides have the same function as human OCP protein does. Therefore, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

With limited disclosure provided by the specification, the skilled artisan cannot envision all the possible polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co.* Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated polypeptide encoded by a nucleic acid molecule consisting of SEQ ID No: 23 meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 14-16, 18, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 1 is rejected as vague and indefinite in view of the phrase "or comprising a sequence incorporated in a plasmid designated pCm-H608-N-term, deposited under ATCC Accession No. PTA-3638 and a polynucleotide having a sequence that differs from SEQ ID NO: 1, SEQ ID NO:3, SEQ ID NO:6, SEQ ID NO: 20, SEQ ID NO: 22, SEQ ID NO: 23" because, from the phrase, it appears that the sequence incorporated in a plasmid designated pCm-H608-N-term and the polynucleotide having a sequence that differs from the sequence selected from SEQ ID NO: 1, SEQ ID NO:3, SEQ ID NO:6, SEQ ID NO: 20, SEQ ID NO: 22, SEQ ID NO: 23 are two different nucleic acids, which is opposite from the specification wherein the polynucleotide having a sequence that differs from SEQ ID NO: 1, SEQ ID NO:3, SEQ ID NO:6, SEQ ID NO: 20, SEQ ID NO: 22, SEQ ID NO: 23 is inserted into the plasmid designated pCm-H608-N-term (see page 34, second paragraph). Please clarify.

13. Claim 1 is rejected as vague and indefinite in view of the phrase "a sequence incorporated in a plasmid designated pCm-H608-N-term, deposited under ATCC Accession No. PTA-3638 due to the degeneracy of the genetic code or a function portion thereof or a polynucleotide which is at least substantially homologous or identical thereto" because it is unclear what it intended. For example, it is known in the art that the degeneracy of the genetic code is related to protein translation. However, from the phrase, it is unclear how the degeneracy of the genetic code is correlated with translation of the nucleotide sequence incorporated in the plasmid designated

pCm-H608-N-term. Furthermore, it is unclear which nucleic acid in the claim is related to "a function portion thereof" or "a polynucleotide which is at least substantially homologous or identical thereto". Please clarify.

14. Claims 14 and 15 recite the limitation "claim 13" in the claims. There is insufficient antecedent basis for this limitation in the claims since claim 13 was deleted by applicant.

15. Claim 32 recites the limitation "the isolated polypeptide" in the claims. There is insufficient antecedent basis for this limitation in the claims since there is no "an isolated polypeptide" in the claim.

16. Claim 32 is rejected as vague and indefinite in view of the phrase "an expression plasmid designed pCm-H-608-663-N-term". From the claim, it appears that this plasmid has a nucleic acid insert. However, according to the specification, this plasmid does not contain a nucleic acid insert and pCm-H-608-663-N-term is a plasmid used to clone a nucleic acid selected from SEQ ID NO: 1, SEQ ID NO:3, SEQ ID NO: 6, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 23 (see page 34, second paragraph). Please clarify.

Conclusion

15. No claim is allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993),

and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
February 19, 2003

Ethan Whisenant, Ph. D.
Primary Examiner (FSA)